

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Li, G.L. *et al.*
Serial No.: **10/713,424**
Filed: November 17, 2003
Title: IONTOPHORETIC DELIVERY OF ROTIGOTINE FOR THE
TREATMENT OF PARKINSON'S DISEASE
Group Art Unit: 1617
Examiner: D.R. Claytor
Confirmation No.: 4527
Docket No.: **6102-000071/US**
Client Ref.: P/Wo/IX/12/02

SUBMITTED ELECTRONICALLY VIA EFS-WEB

16 February 2010

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705(d)

1. This is a request for reconsideration of the patent term adjustment of 797 days under 35 U.S.C. §154(b) indicated on the face of above-identified patent. It is respectfully requested that Patentee be granted a minimum patent term adjustment of 1466 days.
2. The above-identified patent issued on 15 December 2009. Because 15 February 2010 fell on a U.S. Government Holiday (President's Day), the due date is the next open business day, 16 February 2010. Accordingly, as required by 37 C.F.R. §1.70(d), the instant request is timely filed within two months of the issue date of the above-identified patent.
3. Patentee submits herewith a "Statement of the Facts" as described in 37 C.F.R. §1.75(b)(2).

4. In accordance with 37 C.F.R. §1.75(b)(1), please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Account No. **08-0750**.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

/ Leanne M. Rakers /

Leanne M. Rakers
Attorney for Applicant
Reg. No. 64,412
Harness, Dickey & Pierce, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, Missouri 63105
314.726.7514 (direct)
314.726.7501 (fax)

Enclosures:

Statement of Facts Under 37 C.F.R. §1.705(b)(2)
Exhibit A: U.S. Patent No. 7,632,859 (front page)
Exhibit B: Office PTA Sheet
Exhibit C: Timeline Illustration

646382.47.1

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MS Petition
Commissioner for Patents
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Sir:

**STATEMENT OF THE FACTS IN SUPPORT OF REQUEST FOR RECONSIDERATION
OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(d)**

1. This statement is respectfully submitted in support of the "Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. §1.705(d)" for the above referenced patent, which is not subject to a terminal disclaimer (see Exhibit A). In view of the following, it is respectfully requested that Patentee be granted a final term adjustment of **1466 days**.

2. Pursuant to 37 C.F.R. §1.703(b), Patentee is entitled to a period of patent term adjustment due to failure of the Office to issue a patent within three years after the date the corresponding application was filed under 35 U.S.C. §111(a), (*i.e.*, by 17 November 2006) (hereinafter "Three Year Delay"). Patentee is entitled to a period of patent term adjustment beginning on the day after the date that is 3 years after the filing date of the application, *i.e.*, 18

November 2006, and ending on the date a Request for Continued Examination was filed, *i.e.*, 19 May 2009. Accordingly, the period of patent term adjustment due to the Three Year Delay by the Office is 914 days. This period of adjustment is 823 days more than the “PTA 36 Months” adjustment of 91 days used by the Office in calculating the patent term adjustment for the above-identified patent. See PTA Sheet submitted herewith as Exhibit B.

However, in addition to the patent term adjustment due to Three Year Delay, pursuant to 37 C.F.R. §1.703(a) Patentee respectfully submits that they are also entitled to a period of Patent term adjustment under § 1.702(a) (hereinafter “Examination Delay”) which is the sum of the following periods of delay:

(1) A period of delay of 795 days due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by 17 November 2003) (hereinafter “14 Month Delay”). As the Office failed to mail an action under 35 U.S.C. §132 until 23 March 2007, Patentee is entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above referenced application was filed under 35 U.S.C. §111(a), *i.e.*, 18 November 2006, and ending on the date of mailing of an action under 35 U.S.C. §1.32, *i.e.*, 23 March 2007. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 795 days, which is in agreement with the period calculated by the Office (see Exhibit B).

(2) A period of delay of 28 days due to the failure by the Office to mail a Non-Final Office Action not later than four months after Patentee submitted a response to a previous action (hereinafter “4 Month Examination Delay”). Patentee submitted a Response to Non-Final Office Action on 22 September 2008. Since the Office failed to mail a subsequent Non-Final Rejection until 19 February 2009, Patentee is entitled to a period of patent term adjustment beginning on the day after the date that is 4 months after the date on which the Response was filed, *i.e.*, 23 January 2009, and ending on the date the Office mailed the subsequent Non-Final Office Action, *i.e.*, 19 February 2009. Therefore, the period of patent term adjustment due to the 4 Month Examination Delay is 28 days, which is in agreement with the period calculated by the Office (see Exhibit B).

Accordingly, Patentee is entitled to a total period of Examination delay of 823 days, which is the sum of the period of 14 Month Delay (795 days) and the period of 4 Month Examination Delay (28 days).

As set forth in 37 CFR §1.703(f), Patentee is entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 (hereinafter “Office Delay”) reduced by the period of time equal to the period of time during which Patentee failed to

engage in reasonable efforts to conclude prosecution pursuant to 37 C.F.R. §1.704 (hereinafter “Applicant Delay”). With respect to the above referenced application, the total period of Office Delay is the sum of the period of Three Years Delay (914 days) and the period of Examination Delay (823 days). Since the period of 14 Month Delay did not end prior to the first day of the period of Three Year Delay, *i.e.* 18 November 2006, Patentee submits these periods overlap by 126 Days. Similarly, the 28 days of the 4 Month Examination Delay overlaps with the period of Three Year Delay. Patentee encloses a timeline which illustrates this overlap (see Exhibit C). Accordingly, Patentee submits that the total period of Office Delay is 1583 days, which is the sum of the period of Three Year Delay (914 days) and the period of Examination Delay (823 days), reduced by the period of overlap (154 days).

To calculate the period of patent term adjustment, the total period of Office Delay is reduced by the period of Applicant Delay, which the USPTO calculated as a period of 117 days (see Exhibit B). Accordingly, Patentee submits that the correct patent term adjustment for the above referenced application is 1466 days, which is the difference between the total period of Office Delay (1583 days) and the period of Applicant Delay (117 days).

In view of the foregoing, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 1466 days.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

/ Leanne M. Rakers /

Leanne M. Rakers
Attorney for Applicant
Reg. No. 64,412
Harness, Dickey & Pierce, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, Missouri 63105
314.726.7514 (direct)
314.726.7501 (fax)



US007632859B2

(12) **United States Patent**
Li et al.

(10) **Patent No.:** **US 7,632,859 B2**
 (45) **Date of Patent:** **Dec. 15, 2009**

- (54) **IONTOPHORETIC DELIVERY OF ROTIGOTINE FOR THE TREATMENT OF PARKINSON'S DISEASE**
- (75) **Inventors:** Gai Ling Li, Middlesex (GB); Johanna Aaltje Bouwstra, Barendrecht (NL); Hans-Michael Wolff, Monheim (DE); Akhmad Karis Nugroho, Leiden (NL)
- (73) **Assignee:** Schwarz Pharma AG, Monheim (DE)
- (*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 797 days.
- (21) **Appl. No.:** 10/713,424
- (22) **Filed:** Nov. 17, 2003
- (65) **Prior Publication Data**
 US 2004/0116537 A1 Jun. 17, 2004
- (30) **Foreign Application Priority Data**
 Dec. 2, 2002 (EP) 02026871

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(Continued)

- (51) **Int. Cl.**
 A01N 43/06 (2006.01)
 A61K 31/38 (2006.01)
 A61N 1/30 (2006.01)
- (52) **U.S. Cl.** 514/438; 514/443; 604/20
- (58) **Field of Classification Search** 514/438
 See application file for complete search history.

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Primary Examiner—Sreeni Padmanabhan
Assistant Examiner—Renee Claytor
 (74) *Attorney, Agent, or Firm*—Harness, Dickey & Pierce, P.L.C.

(57) ABSTRACT

By using a composition comprising rotigotine and at least one chloride salt in a concentration of 1 to 140 mmol/l, the composition having a pH of 4 to 6.5 in a iontophoretic device for the treatment of Parkinson's disease, it became possible to obtain a rotigotine flux across the human stratum corneum which was higher than the one previously obtained with conventional passive diffusion systems.

12 Claims, No Drawings



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10/713,424

IONTOPHORETIC DELIVERY OF ROTIGOTINE FOR THE TREATMENT OF PARKINSON'S DISEASE

Select New Case	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Foreign Priority	Fees	Published Documents	Address & Correspondence Agents
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Patent Term Adjustment

Filing or 371(c) Date:	11-17-2003	USPTO Delay (PTO) Delay (days):	-
Issue Date of Patent:	12-15-2009	Three Years:	-
Pre-Issue Petitions (days):	-	Applicant Delay (APPL) Delay (days):	-
Post-Issue Petitions (days):	-	Total Patent Term Adjustment (days):	797
USPTO Adjustment (days):	-	Explanation Of Calculations	1

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
11-24-2009	PTA 36 Months	91	
12-15-2009	Patent Issue Date Used in PTA Calculation		
11-06-2009	Dispatch to FDC		⬆
11-05-2009	Application Is Considered Ready for Issue		⬆
11-02-2009	Issue Fee Payment Verified		⬆
11-02-2009	Issue Fee Payment Received		⬆
08-18-2009	Mail Notice of Allowance		⬆
08-10-2009	Document Verification		⬆
08-10-2009	Notice of Allowance Data Verification Completed		⬆
05-19-2009	Information Disclosure Statement considered		⬆
05-19-2009	Electronic Information Disclosure Statement		⬆

05-20-2009	Date Forwarded to Examiner	✦	
05-20-2009	Date Forwarded to Examiner	✦	
05-19-2009	Request for Continued Examination (RCE)	✦	
05-20-2009	Disposal for a RCE / CPA / R129	✦	
05-19-2009	Information Disclosure Statement (IDS) Filed	✦	
05-19-2009	Workflow - Request for RCE - Begin	✦	
02-19-2009	Mail Final Rejection (PTOL - 326)		28
02-17-2009	Final Rejection	✦	
12-10-2008	Date Forwarded to Examiner	✦	
09-22-2008	Response after Non-Final Action	✦	
06-25-2008	Mail Non-Final Rejection		
06-23-2008	Non-Final Rejection		
03-14-2008	Information Disclosure Statement considered		
03-14-2008	Reference capture on IDS		
03-14-2008	Information Disclosure Statement (IDS) Filed		
04-03-2008	Date Forwarded to Examiner		
03-14-2008	Response after Non-Final Action		91
03-14-2008	Request for Extension of Time - Granted	✦	
03-14-2008	Information Disclosure Statement (IDS) Filed	✦	
10-29-2007	Change in Power of Attorney (May Include Associate POA)	✦	
10-26-2007	Correspondence Address Change	✦	
09-27-2007	Change in Power of Attorney (May Include Associate POA)	✦	
09-27-2007	Correspondence Address Change	✦	
09-14-2007	Mail Non-Final Rejection	✦	
09-13-2007	Non-Final Rejection		
07-19-2007	Information Disclosure Statement considered		
07-19-2007	Reference capture on IDS		
07-19-2007	Information Disclosure Statement (IDS) Filed		
07-19-2007	Information Disclosure Statement (IDS) Filed		

07-22-2007	Date Forwarded to Examiner		
07-19-2007	Response after Non-Final Action		26
07-19-2007	Request for Extension of Time - Granted		*
03-23-2007	Mail Non-Final Rejection	795	
03-19-2007	Non-Final Rejection	*	
02-17-2004	Information Disclosure Statement considered	*	
03-08-2007	Case Docketed to Examiner in GAU	*	
04-21-2005	Case Docketed to Examiner in GAU	*	
11-29-2004	Correspondence Address Change	*	
04-01-2004	Case Docketed to Examiner in GAU	*	
04-01-2004	Reference capture on IDS	*	
02-17-2004	Information Disclosure Statement (IDS) Filed	*	
02-17-2004	Information Disclosure Statement (IDS) Filed	*	
11-17-2003	Preliminary Amendment	*	
03-22-2004	IFW TSS Processing by Tech Center Complete	*	
03-11-2004	Application Return from OIPE	*	
03-11-2004	Application Return TO OIPE	*	
03-11-2004	Application Return from OIPE	*	
03-11-2004	Application Is Now Complete	*	
03-11-2004	Application Return TO OIPE	*	
03-11-2004	Application Dispatched from OIPE	*	
03-11-2004	Application Is Now Complete	*	
02-23-2004	Payment of additional filing fee/Preexam	*	
02-23-2004	Small Entity Statement (37 CFR 1.27)	*	
02-23-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant	*	
02-13-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	*	
02-02-2004	Cleared by OIPE CSR	*	
12-22-2003	IFW Scan & PACR Auto Security Review	*	

11-17-2003 Initial Exam Team nn



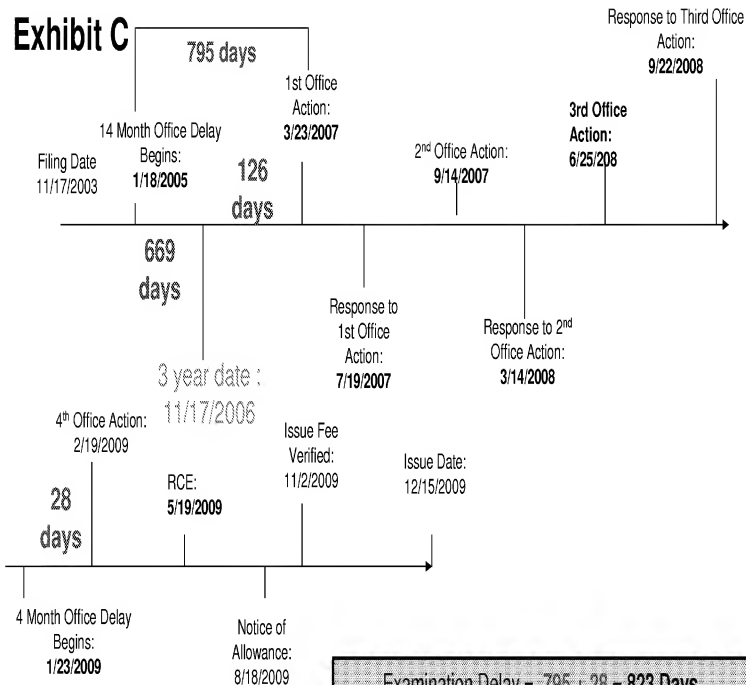
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Exhibit C



Examination Delay = $795 + 28 = \underline{823 \text{ Days}}$

3 Year Delay = $\underline{914 \text{ Days}}$

Overlap = $126 + 28 = \underline{154 \text{ Days}}$

Total PTA = $823 + 914 - 154 - 117 = \underline{1466 \text{ Days}}$